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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/423,698 02/10/00 LEROY

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HM12/0515

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FIELDS, I	
ART UNIT	PAPER NUMBER

1645

8

DATE MAILED:

05/15/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)
	09/423,698	LEROY, ODILE
	Examiner	Art Unit
	Iesha P Fields	1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) _____ is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-23 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) Notice of References Cited (PTO-892)
- 16) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 18) Interview Summary (PTO-413) Paper No(s). _____.
- 19) Notice of Informal Patent Application (PTO-152)
- 20) Other: _____.

DETAILED ACTION

Applicant's preliminary amendment filed February 10, 2000 (Paper No. 5) has been received and entered.

Claim Rejections - 35 USC § 112

1. Claims 1-23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The claims recite a composition comprising "n" conjugates derived from *Streptococcus pneumoniae*. The specification and claims do not indicate what distinguishing attributes are shared by all of the serotypes/serogroups of *Streptococcus pneumoniae*. Thus, the scope of the claims includes numerous structural variants. Since the disclosure fails to describe the common attributes or characteristics that identify all of the members encompassed by the claimed invention, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of all of the serotypes/serogroups of *Streptococcus pneumoniae*.

_____ Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The protein itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

2. Claims 1-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) The claims are vague and indefinite in the recitation of a composition comprising "n" conjugates. One skilled in the art would be unable to determine the meets and bounds of such a limitation. For instance, which conjugates of Streptococcus is the applicant claiming and exactly how many does "n" encompass? Without a clear definition as to which conjugates and exactly how many the applicant intends to be encompassed by the claims one of skill in the art would be unable to replicate the broadly claimed invention.

B) Claims 1 and 14 are vague and indefinite in recitation of "especially" 12 to 15 conjugates. One skilled in the art would be unable to determine the meets and bounds of such a limitation. For instance, would 11 to 16 conjugates fall within the range of the claimed invention? Without a clear definition as to the number of conjugates encompassed by the claims one of skill in the art would be unable to replicate the claims.

C) Claims 1-23 are vague and indefinite in recitation of "derived" from *Streptococcus pneumoniae*. One skilled in the art would be unable to determine the meets and bounds of such a limitation. For instance, derived from may encompass unknown modifications to the protein. Without a more clear definition one of skill in the art would be unable to replicate the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1- 9 and 12-15 are rejected under 35 U.S.C. 103(a) as being anticipated by Marburg et al. in view of Matuhashi et al.

The claims are drawn to a conjugate composition comprising capsular polysaccharide from *Streptococcus pneumoniae* bacteria linked to immunogenic carrier proteins.

Marburg et al (US Patent 5,623,057) teach of a conjugate vaccine comprising capsular polysaccharide from *Streptococcus pneumoniae* (Pn) linked to an immunogenic carrier protein. Marburg et al. further teach that composition comprises a mixture of one to ten different pneumococcal polysaccharide-immunogenic protein conjugates. Marburg et al further teach that the polysaccharide may be derived from any of the subtypes of *Streptococcus pneumoniae* including 1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19F, 19A, 20, 22F, 23F, and 33F (See entire document).

Marburg et al does not teach of a conjugate composition comprising capsular polysaccharide from *Streptococcus pneumoniae* linked to more than one immunogenic carrier protein.

Matuhashi et al. (US Patent 4,372,883) teach of a process for the production of vaccines characterized by covalent attachment of a biologically toxic substance to a

saccharide to form a biologically toxic substance-saccharide conjugate. Matuhashi et al. further teach that the preparation may include tetanus toxin (Tt) or diphtheria toxin (Dt) (See entire document; especially examples).

Given that 1) Marburg et al. has taught of a conjugate vaccine comprising capsular polysaccharide from *Streptococcus pneumoniae* linked to an immunogenic carrier protein and that 2) Matuhashi et al. has taught of a process for the production of vaccines characterized by covalent attachment of a biologically toxic substance to a saccharide to form a biologically toxic substance-saccharide conjugate it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to make a conjugate composition comprising capsular polysaccharide from *Streptococcus* linked to more than one immunogenic carrier protein such as Dt or Tt. One would have been motivated to make such a composition in view of the teachings of Matuhashi et al. that carrier proteins (i.e. PT, Dt and Tt) when incorporated in conjugate vaccines illicit a strong immune response that is effective and safe in potential human vaccines. One of ordinary skill in the art would reasonably expect that the incorporation of an additional carrier protein would boost the immunological response.

4. Claims 1, 8-11, and 16-23 are rejected under 35 U.S.C. 103(a) as being anticipated by Marburg and Matuhashi et al. in view of Peeters et al.

The claims are drawn to a conjugate composition comprising capsular polysaccharide from Streptococcus linked to a carrier protein which has a quantity less the 50 ug/dose.

The teachings of Marburg and Matuhashi et al. are set forth above.

Marburg and Matuhashi et al. do not teach of a conjugate composition comprising capsular polysaccharide from Streptococcus linked to a carrier protein which has a quantity less the 50 ug/dose.

Peeters et al. (Infection and Immunity 1991 Vol 59(10) pp. 3504-3510) teach of immunizing animals with a saccharide-protein conjugate which has a quantity of less the 50 ug/dose.

Given that 1) Marburg and Matuhashi et al. have taught of a conjugate vaccines comprising bacterial polysaccharides linked to immunogenic carrier proteins and that 2) Peeters et al. has taught of immunizing animals with a saccharide-protein conjugate which has a quantity of less the 50 ug/dose it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to make a conjugate vaccine comprising capsular polysaccharide from Streptococcus linked to a carrier protein which has a quantity less the 50 ug/dose. One would have been motivated to make a conjugate composition comprising capsular polysaccharide from Streptococcus linked to a carrier protein which has a quantity less the 50 ug/dose in view of the teachings of

Peeters et al. which found that animals immunized with low doses of DT generated higher levels antipolysaccharide antibodies.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to lescha P Fields whose telephone number is (703) 605-1208. The examiner can normally be reached on 7am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

lesha Fields

May 7, 2001


MARK NAVARRO
PRIMARY EXAMINER